DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 23, 2015

Cynosure Incorporated
Ms. Aastha Kohli
Senior Regulatory Affairs Specialist
5 Carlisle Road
Westford, Massachusetts 01886

Re: K141511
Trade/Device Name: SideLaze800™ Laser Beam Delivery Accessory for Cynosure 1440nm Wavelength Lasers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: December 18, 2014
Received: December 19, 2014

Dear Ms. Kohli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141511

Device Name
SideLaze800™Laser BeamDelivery Accessory for Cynosure 1440nmWavelength Lasers

Indications for Use *(Describe)*
SideLaze800™ is an accessory to deliver optical energy for Cynosure 1440nm wavelength lasers and intended to be used with Cynosure 1440nm wavelength lasers for surgical incision, excision, vaporization, ablation, and coagulation of soft tissue (including skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and gland) laser assisted lipolysis and the treatment of primary axillary hyperhidrosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5 **510K Summary**

510(k) Summary for SideLaze800™ Laser Beam Delivery Accessory

A. Sponsor

Cynosure, Inc.
5 Carlisle Road
Westford, MA 01886

B. Contact

Ms. Aastha Kohli
Senior Regulatory Affairs Specialist
781-993-2394
akohli@cynosure.com

C. Device Name

Trade Name:	SideLaze800™ Laser Beam Delivery Accessory for Cynosure 1440nm Wavelength Lasers
Common/usual Name:	Powered Laser Surgical Instrument (Laser for Surgery and Dermatology)
Classification Name:	GEX-Powered laser surgical instrument, General & Plastic Surgery 21 CFR 878.4810, Class II

D. Predicate Device

Trade Name:	SideLaze800™ Laser Beam Delivery Accessory for Cynosure 1440nm Wavelength Lasers
Common/usual Name:	Powered Laser Surgical Instrument (Laser for Surgery and Dermatology)
Classification Name:	GEX-Powered laser surgical instrument, General & Plastic Surgery 21 CFR 878.4810, Class II
Premarket Notification:	Cynosure Inc, K121127 (05/13/2012)
Trade Name:	miraDry System
Common/usual Name:	Microwave And Accessories
Classification Name:	NEY-System, Ablation, Microwave and Accessories, General & Plastic Surgery 21 CFR 878.4400, Class II
Premarket Notification:	Miramar Labs, Inc., K103014 (01/08/2011)

E. Device Description

The Cynosure 1440nm Wavelength laser is solid state Nd: YAG laser, having a neodymium rod as a lasing medium. Laser activation is by footswitch. Overall weight of the laser is 220lbs, and the size is 38.6"x16.5"x35.5" (HxWxD). Electrical requirement is 230 VAC, 16A, 50-60 Hz, single phase. SideLaze800™ Laser Beam Delivery Accessory is an optional side-firing fiber optic accessory used with the Cynosure Lasers with 1440nm wavelength. The SideLaze800™ option is intended to offer physicians a convenient accessory.

SECTION 5 510K Summary

F. Intended Use/Indications for Use

SideLaze800™ is an accessory to deliver optical energy for Cynosure 1440nm wavelength lasers and intended to be used with Cynosure 1440nm wavelength lasers' for surgical incision, excision, vaporization, ablation, and coagulation of soft tissue (including skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and gland), laser assisted lipolysis and the treatment of primary axillary hyperhidrosis.

G. Technological Characteristics

The SideLaze800™ option contains equivalent components and patient-contacting materials as previously cleared SideLaze800 Laser Beam Delivery Accessory for Cynosure 1440nm Wavelength Lasers (K121127). There is no change in device design or performance characteristics compared to previously cleared device. This proposed SideLaze800™ Fiber will have an additional indication for use for the treatment of primary axillary hyperhidrosis.

SECTION 5 **510K Summary**

	Proposed Device	**Predicate Device**	**Predicate Device**
510(k)#	K141511	K121127	K103014
Manufacturer	Cynosure, Inc.	Cynosure, Inc.	Miramar Labs, Inc.
Device Name	SideLaze800™, Laser Beam Accessory for Cynosure 1440nm Wavelength Lasers	SideLaze800™, Laser Beam Accessory for Cynosure 1440nm Wavelength Lasers	miraDry System
Clearance Date	TBD	May 13, 2012	January 8, 2011
Classification/ Regulation	Class II/21 CFR 878.4810	Class II/21 CFR 878.4810	Class II/21 CFR 878.4400
Indications for Use	SideLaze800™ is an accessory to delivery optical energy for Cynosure 1440nm wavelength lasers and intended to be used with Cynosure 1440nm wavelength lasers' cleared indications for use, such as the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue (including skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and gland) laser assisted lipolysis and the treatment of primary axillary hyperhidrosis.	SideLaze™ is an accessory to deliver optical energy for Cynosure 1440nm wavelength lasers and intended to be used with Cynosure 1440nm wavelength lasers' cleared indications for use, such as the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue (including skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscile, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands) and laser assisted lipolysis. SideLaze800™ may be used in combination with a Cynosure SMA-compatible laser system for the same indications	The miraDry System is indicated for use in the treatment of primary axillary hyperhidrosis.
Use Principle	Delivers focused laser energy for surgical incision, excision, vaporization, ablation, and coagulation of soft tissue, which includes ablation of sweat glands.	The SideLaze800™ Laser Beam Delivery Accessory targets the sweat glands in the underarm area and uses focused laser energy to ablate their function.	MiraDry utilizes microwave energy, for the reduction or removal of sweat glands.
Wavelength	1440 nm	1440 nm	[redacted]
Pulse Characteristics:			
Maximum Delivered Energy Limit	300 J/cm^2	300 J/cm^2	
Fiber Optic Characteristics:			
Diameter	800 µm	800 µm	
Length	3 meters	3 meters	
Aiming Beam	632.8 nm (wavelength)	632.8 nm (wavelength)	

H. Clinical Information

Clinical testing showed that the device provides a safe and effective means to treat axillary hyperhidrosis using the SideLaze800™ Laser Beam Delivery Accessory. There were 59 subjects enrolled at 4 study centers, all subjects underwent single treatment and were followed up till 12 months. Treatment effectiveness was assessed through subject rated Hyperhidrosis Disease Severity Scale (HDSS) scores at each follow up visit, Physician Satisfaction Scale (PSS), blinded evaluation of pre and post photographs from starch iodine test results obtained at each follow up visit and recording of adverse events. Ninety Eight percent subjects returned for the three month follow up visit, Ninety six percent returned for the six month follow-up visit, eighty six percent returned for the nine month and twelve month follow up. All subjects demonstrated a reduction, ablation and fragmentation of the sweat glands. There were no deaths, serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) reported in these studies.

I. Substantial Equivalence

There is no change in the SideLaze800™ accessory's design, principle of operation, material of construction and intended use compared to the previously cleared accessories for the Cynosure Lasers with 1440nm wavelength. The proposed indication for use "Primary axillary hyperhidrosis" is supported with clinical evidence demonstrating SideLaze800™ safety and effectiveness.